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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,840	10/23/2003	Sheldon R. Pinnell	SKIC02	6687

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,840	PINNELL, SHELDON R.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in the application and were examined on their merits.

Election/Restrictions

Applicant's election without traverse of the species of *C. asiatica*, ecotin and lipid complex in the reply filed on 5/9/05 is acknowledged.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 does not contain a period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-19 either recite, or depend upon a claim which recites 'extract of *Centella asiatica*. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts. It is also noted that claims 1 and 4-19 lack written description for the entirety of the phrases 'a first component supporting skin collagen structure' and 'a second component that supports body defense and repair mechanisms'. It is deemed that Applicant was not in possession of the entire genus of these products which are only described in these claims by their function rather than by a physical description.

Claim 19 also recites the term 'dipeptide'. It is deemed that Applicant was not in possession of every known dipeptide.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* extracts. Further, claim 19 is directed

toward *all potential* dipeptides. The possible variations of extracts are limitless. Although Applicant has disclosed a titrated extract of *Centella asiatica* with specific properties as disclosed on page 4 of the Instant specification, one is *a very small number* in comparison to the enormous, *potentially thousands* of types of extracts which could be obtained from *Centella asiatica*. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example:

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction (CO_2) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a seperatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the plant to obtain a juice: the product is an extract.

6) dipping the plant in an organic solvent to remove the waxy layer: the product is an extract.

Further, although Applicant has disclosed the peptide Pal-GQPR, this one species of peptide is not representative of all known dipeptides and thus, it is deemed that Applicant was not in possession of such a large genus of dipeptides.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F. 3d at 1572, 41 USPQ2d at

1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The specification lacks sufficient variety of species of extracts to reflect this variance in the genus since the specification does not provide sufficient examples of such a genus of extracts.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of 'extract' and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al. (US 6,203,805 B1).

Colins et al. (US 6,203,805 B1) discloses a topical composition comprising 'collagen enhancing effective amounts of a whey protein, a retinoid, a vitamin E or derivatives thereof and an ascorbic acid or derivatives thereof...' (see claim 1). Thus, it is clear that whey protein and vitamin E both support collagen structure, and vitamin E naturally possesses antioxidant properties which help the skin "...repair and protect itself against premature aging" Jane, M (2001).

Thus, Collins et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4 and 13 - 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (US 6,203,805 B1).

The teachings of Collins et al. were discussed *supra*.

Collins et al. did not disclose a particular embodiment which included a first component which supported skin collagen structure, a second component that supports body defense and repair mechanisms and a third component that supports skin lipids. Collins et al. also did not teach wherein their composition included a plant extract such as glycolipids, fatty acids and triglycerides from sandal wood, cork tree bark and barley grains.

Collins et al. did, however, disclose that mineral oil would have been a suitable carrier for the active ingredients of whey protein and vitamin E (see for example, col. 5, lines 16-17). It is well known that oils contain triglycerides. It is also well known that fatty acids and glycolipids are obvious variants of triglycerides and that each could be interchanged with another or alternatively, added together in order to improve the quality of skin.

Claims 11-12, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. as applied to claims 1, 3, 4 and 13 - 15 above, and further in view of Cope (US 6,572,868 B1).

The teachings of Collins et al. were discussed *supra*. Collins et al. did not teach wherein a firming agent was added to the composition.

Cope utilizes dipalmitoyl hydroxyproline as well as ceramides such as ceremides III and VI, in a composition for restructuring skin (see the Abstract for example). Cope specifically explains that "Dipalmitoyl hydroxyproline is believed to be effective in preventing and/or treating the effects of skin ageing and in firming the skin including for increasing collagen synthesis" (Col. 4, lines 15-17). Dipalmitoyl hydroxyproline is an amino acid derived from plants.

One of ordinary skill in the art would have been motivated to add dipalitoyl hydroxyproline and ceramides to the composition of Collins et al. in order to impart further collagen synthesis as well as for additional skin firming. It is clear that the addition of dipalitoyl hydroxyproline would therefore result in an additive effect on collagen synthesis and thus provide for an improved composition.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. in view of Cope as applied to claims 11-12, 16 and 18 above, and further in view of Pirisi, A. (1998).

The teachings of Collins et al. and Cope were discussed *supra*. Neither reference specifically taught wherein ceramide 1 or cholesterol was added to their composition.

It is noted that Cope did specifically teach ceremides III and VI and also taught that these ceremides were types of phytosphingosines. Thus, it is deemed that the choice of ceremides (i.e., I, III or VI) would have been considered routine judicial selection on the part of the ordinary practitioner because they are deemed obvious variants of one another.

One of ordinary skill in the art would have been motivated to add ceremide 1 into the composition in order to impart further softening ability to the topical composition of Collins et al.

Pirisi, A. (1998) reported that cholesterol was added to lotion as a moisturizing ingredient (see page 2, sentence beginning 'As for Estee Lauder...'.

Thus, one of ordinary skill in the art would have been motivated to add cholesterol to a topically applied composition in order to impart additional moisture to the composition.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069; 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

Claims 2, 5-10 and 19 are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

April 14, 2006